

# INTRAVASCULAR CATHETER WITH AXIAL MEMBER

## Cross Reference to Related Applications

The present invention is related to U.S. Patent Application No. 09/234,203, filed January 20, 1999, entitled "INTRAVASCULAR CATHETER WITH COMPOSITE REINFORCEMENT"; and U.S. Patent Application No. (unknown), filed on even date herewith, entitled "INTRAVASCULAR CATHETER WITH MULTIPLE AXIAL MEMBERS", the entire disclosures of which are hereby incorporated by reference.

## Field of the Invention

The present invention generally relates to intravascular catheters. More specifically, the present invention relates to intravascular catheters having braid reinforcement.

## Background of the Invention

Intravascular catheters are used in a wide variety of relatively non-invasive medical procedures. Such intravascular catheters may be used for diagnostic or therapeutic purposes. Generally, an intravascular catheter allows a physician to remotely perform a medical procedure by inserting the catheter into the vascular system of the patient at a location that is easily accessible and thereafter navigating the catheter to the desired target site. By this method, virtually any target site in the patient's vascular system may be remotely accessed, including the coronary, cerebral, and peripheral vasculature.

The distance between the access site and the target site is often in excess of 100 cm. The inside diameter of the vasculature at the access site is often less than 2 cm, and the inside diameter of the vasculature at the target site is often less than 0.5 cm.

Accordingly, intravascular catheters must be relatively long and thin. Furthermore, in order to navigate through the patient's tortuous vascular system, intravascular catheters must be very flexible. It is also desirable that intravascular catheters be relatively soft in order to minimize the probability of damaging vascular tissue.

5           Intravascular catheters typically have a radiopaque portion and are guided through the patient's vascular system with the assistance of x-ray fluoroscopy. A physician may manipulate the proximal end of the catheter and fluoroscopically monitor the corresponding movement of the distal end of the catheter. It is desirable that intravascular catheters be sufficiently radiopaque along their length and particularly at  
10 their distal end such that the physician is able to clearly monitor the progress of the catheter as it is being advanced from the vascular access site to the vascular target site.

After the intravascular catheter has been navigated through the patient's vascular system with the distal end thereof adjacent the target site, the catheter may be used for various diagnostic and/or therapeutic purposes. Frequently, diagnostic and therapeutic  
15 techniques require the infusion of fluids through the catheter. For example, it may be desirable to inject radiopaque contrast media through the catheter to provide enhanced fluoroscopic visualization for diagnostic purposes, or to inject pharmaceutical solutions (i.e., drugs) to the target site for therapeutic purposes. In order to maintain a fluid path, it is desirable that intravascular catheters be sufficiently resistant to kinking. In addition,  
20 because such fluids are delivered under pressure, it is also desirable that intravascular catheters be sufficiently resistant to bursting.

To satisfy some of these desirable features, prior art intravascular catheters have utilized a reinforcement structure such as a braid or coil disposed between an inner

tubular polymer layer and an outer tubular polymer layer. A braid reinforcement structure may provide high resistance to bursting and improve the connection integrity between individual shaft segments. A coil reinforcement structure may provide adequate resistance to ovaling and kinking.

5           Some types of prior art intravascular catheters also utilize longitudinal or axial members to impart stiffness to the catheter shaft. For example, U.S. Patent No. 5,057,092 to Webster discloses an intravascular catheter having a braid reinforcing mesh and longitudinal warp members. The longitudinal warp members are intended to provide increased bending stiffness and thus permit reductions in the wall thickness and/or softer  
10       materials for the inner and outer tubes. The warp members are interwoven with the braid such that warp members alternate under or over the braid mesh. Because the braid reinforcing mesh is disposed between an inner polymeric layer and an outer polymeric layer, portions of the longitudinal warp members are disposed between the braid reinforcing mesh and the adjacent polymeric layer.

15           With this arrangement, the adjacent polymeric layer may conform to the longitudinal warp members so as to create radial protrusions running the length of the catheter. A protrusion along the inside surface of the catheter may not be desirable because it may create friction or bias with devices inserted therein (e.g., guidewires). A protrusion along the outside surface of the catheter may not be desirable because it may  
20       create friction, bias or prevent adequate sealing with devices that the catheter is inserted into (e.g., introducer sheaths, compression fittings, etc.).

          Also with this arrangement, the adjacent polymeric layer may become fixed to the longitudinal warp members as it conforms thereto. Fixing the longitudinal warp

members to the adjacent polymeric layer may not be desirable because it may limit relative movement and flexure therebetween. Limiting relative movement and flexure may cause excessive stiffness in one or more planes of flexure. This may cause difficulties in manipulating and navigating the catheter through tortuous vasculature, which is clearly undesirable.

Accordingly, it is desirable to provide the advantages of a longitudinal or axial member without creating a protrusion and without fixing the axial member to the adjacent polymeric layer.

#### Summary of the Invention

The present invention overcomes these disadvantages by providing an intravascular catheter that includes a braid reinforcement with an axial wire or fiber disposed between the helical members that form the braid. By placing the axial member between the helical members, the axial member does not create a protrusion on either side of the braid. In addition, the axial member does not become fixed to any polymer layer adjacent the braid. Thus, the present invention provides the benefits of an axial member, but without the undesirable effects of friction caused by an axial protrusion and without the undesirable effects of limited flexure caused by an adjacent polymer layer becoming fixed to the axial member. Specifically, by utilizing an axial member, the present invention provides a catheter shaft that resists elongation when placed in tension. By resisting elongation, the intravascular catheter of the present invention maintains one-to-one correspondence in axial manipulation thereby maintaining precise control of the catheter.

An intravascular catheter in accordance with one embodiment of the present invention includes an elongate shaft having a lumen extending therethrough. The shaft includes an inner polymer layer, a reinforcement layer disposed about the inner layer and an outer polymer layer disposed about the reinforcement layer. The reinforcement layer comprises a tubular braid having two or more interwoven helical members. The reinforcement layer also includes an axial member disposed between the helical members such that the axial member is retained within the tubular braid structure for at least a length thereof. The axial member may be a wire, fiber, filament, cable or the like, but is generically referred to herein as an axial member.

10 The helical members that form the braid may each comprise polymeric material, a metallic material, or a combination thereof. Similarly, the axial member may comprise a polymeric material or a metallic material. If a polymeric material is utilized for the helical members or the axial member, then each member may comprise a plurality of monofilaments such as LCP. The monofilaments may be held together statically thereby eliminating the need for a binding material that might otherwise add to the profile of the members. To further minimize profile, the monofilaments may be arranged side-by-side to collectively define a flat ribbon or cable.

20 An intravascular catheter in accordance with another embodiment of the present invention includes an elongate shaft having a reinforcement layer. The reinforcement layer comprises a tubular braid of two or more interwoven helical members and an axial member disposed between the helical members. Optionally, the catheter may include inner and/or outer polymer layers disposed on either side of the reinforcement layer.

Each of the inner and/or outer layers may comprise a single layer of polymeric material or multiple layers of polymeric materials.

5 The present invention also provides a method of making such a catheter. The manufacturing method includes the steps of braiding two or more helical members about an axial member such that the axial member is disposed between the helical members. The helical members may be braided over a carrier such as a mandrel that is later removed or a polymeric tubular member that becomes the inner layer of the catheter shaft. After the reinforcement layer is woven about the carrier, another polymeric tubular member may be disposed about the reinforcement layer to become the outer layer of the  
10 catheter shaft.

#### Brief Description of the Drawings

Figure 1 is a plan view of an intravascular catheter in accordance with the present invention;

Figure 2 is fragmentary partially sectioned side view of the shaft of the catheter  
15 illustrated in Figure 1; and

Figure 3 is a cross-sectional view taken along line 3-3 in Figure 1.

#### Detailed Description of the Invention

The following detailed description should be read with reference to the drawings in which similar elements in different drawings are numbered the same. The drawings,  
20 which are not necessarily to scale, depict illustrative embodiments and are not intended to limit the scope of the invention.

Figure 1 illustrates intravascular catheter 10 in accordance with the present invention. Catheter 10 includes an elongate shaft 12 having a proximal region 14 and a

distal region 16. The catheter 10 includes a lumen 18 (as best seen in Figure 3) extending through the entire length of the elongate shaft 12 to an opening at the distal end 20 of the shaft 12. Catheter 10 may have, for example, a length of 80 - 150 cm and an outside diameter of approximately 3F.

5           A manifold 24 is connected to the proximal end 22 of the shaft 12 which includes an interior (not visible) in fluid communication with the lumen 18 of the elongate shaft 12. The manifold 24 includes a standard fitting 26 for connection to a fluid source such as a syringe. A strain relief 28 is disposed between the manifold 24 and the proximal end 22 of the shaft 12 in order to reduce the tendency of the shaft to kink therebetween. The  
10 proximal end 22 of the elongate shaft 12 may extend through the strain relief 28 for connection to the manifold 24. Alternatively, the distal end of the strain relief 28 may be connected to the proximal end 22 of the elongate shaft 12 with the proximal end of the strain relief 12 connected to the manifold 24.

With either arrangement, the intravascular catheter 10 provides a fluid path from  
15 the fitting 26 of the manifold 24 to the distal end 20 of the elongate shaft 12 by way of the interior (not visible) of the manifold 24 and the lumen 18 of the elongate shaft 12. Intravascular catheter 10 may be intravascularly navigated over a guide wire (not shown) and used to deliver diagnostic and/or therapeutic fluids to a desired vascular target site using conventional techniques.

20           Elongate shaft 12 includes a proximal region 14 and a distal region 16. The proximal region 14 is typically more stiff than the distal region 16 in order to provide more pushability for advancing the distal region 16. The distal region 16 is usually more flexible than the proximal region 14 to provide more trackability for navigating tortuous

vasculature. A multi-layer construction may be used in either the proximal region 14 or both the proximal 14 and distal 16 regions, depending on the pushability, trackability, and other characteristics desired for each region.

The multi-layer construction is best seen in Figures 2 and 3. In Figure 2, the outer layer 30 has been removed to expose the braid reinforcement layer 50 comprising helical members 32 (individually designated as 32A and 32B) and the axial member 34. The helical members 32 and the axial member 34 are each shown as a set of monofilaments 40, but may also comprise a single monofilament 40. The multi-layer construction includes the inner lubricious polymer layer 36 surrounded by the braid reinforcement layer 50 which, in turn, is surrounded by the outer layer 30. A tie layer 38 may be provided between the braid reinforcement layer 50 and the inner lubricious layer 36.

The inner layer 36 may be formed of a lubricious polymer such as PTFE or HDPE and preferably has a relatively thin wall to minimize profile. Inner layer 26 has an inside diameter sufficiently large to accommodate a conventional guidewire and to accommodate the delivery of fluids therethrough at a sufficient flow rate. For example, the inside diameter of the inner layer 36 may be approximately 0.027 inches and the wall thickness of the inner layer 36 may be approximately 0.0005 inches. The inner layer 36 may be formed, for example, by coating or extruding a lubricious polymer such as PTFE over a removable mandrel, or by using other known manufacturing techniques.

The tie layer 38 may be utilized to secure the helical members 32 to the inner lubricious layer 36. The tie layer 38 enhances the bond between the inner lubricious layer 36, the helical members 32, and the outer layer 30. Tie layer 38 also fills any micro-pores that may form in the inner layer 36 to thereby increase burst strength.



Further, tie layer 38 maintains the position of the helical members 32 on the inner layer 36 during the manufacturing process. The thickness of the tie layer 38 may be approximately 0.0003 inches to reduce the corresponding increase in profile. An example of a suitable material for tie layer 38 is polyurethane, which may be coated onto the inner lubricious layer 36.

As seen in Figures 2 and 3, the helical members 32 are interwoven to form a tubular braid. For purposes of illustration, only two helical members 32A and 32B are shown. Those skilled in the art will recognize that the braided helical members 32 may vary in number, pattern, pick-count, etc., without departing from the scope of the present invention. The helical members 32 may comprise a polymeric material, a metallic material or a combination thereof. Polymeric helical members 32 provide superior flexibility and softness, metallic helical members 32 provide superior radiopacity and kink resistance, and a combination of polymeric and metallic helical members 32 provide all these attributes.

If metallic materials are utilized, the helical members 32 may comprise stainless steel, nickel-titanium alloy, or a highly radiopaque material such as gold, tungsten, iridium, or an alloy thereof. If a plurality of metallic helical members 32 are utilized, one or more of the metallic helical members 32 may comprise stainless steel to provide superior strength and one or more of the other metallic helical members 32 may comprise a highly radiopaque material to provide enhanced radiopacity. Although stainless steel provides higher radiopacity relative to most polymers, a more dense material such as those identified above are preferred for purposes of radiographic visualization. The metallic helical members 32 may have a rectangular cross-section or a circular cross-

section, depending on the desired mechanical characteristics and the desired effect on profile. For example, metallic helical members 32 may have a circular cross-section with a diameter of approximately 0.0016 inches.

If polymeric materials are utilized, the helical members 32 may comprise a single monofilament 40 or a plurality of monofilaments 40 as shown. The plurality of monofilaments 40 may be unfused or fused together depending on the desired characteristics. Unfused monofilaments 40 may be held together statically thereby eliminating the need for a binding material that might otherwise add to the profile of the shaft 12. To further minimize profile, the monofilaments 40 may be arranged side-by-side to collectively define a flat ribbon or cable, as best seen in Figure 3.

Fused monofilaments 40 provide the helical members 32 with mechanical characteristics similar to that of a solid rod. Unfused monofilaments 40 held together statically provide the helical members 32 with mechanical characteristics similar to that of a cable. A cable, as opposed to a solid rod, is more flexible and is able to withstand more fatigue from repeated bending. As such, helical members 32 comprising a plurality of monofilaments 40 held together statically provide a shaft 12 that is more flexible and more durable. These features are significant because the catheter 10 must be able to navigate tortuous vasculature and withstand harsh handling conditions.

The monofilaments 40 may be made of a liquid crystal polymer (LCP) available under the trade name VECTRAN. Each monofilament 40 may have a circular cross-section having a diameter of 0.0007 inches. Each helical member 32 may comprise two (2) to ten (10), and preferably five (5) monofilaments 40 which, as stated previously, may be fused or unfused. The monofilaments 40 are preferably unfused and arranged side-by-

side to essentially define a flat cable or ribbon. It is possible, however, that the monofilaments 40 be arranged in any manner to collectively define any other desired geometry.

The axial member 34 is disposed between the helical members 32A and 32B.

5 Axial member 34 may comprise any of the same or similar structures and materials as helical members 32. Preferably, the axial member 34 comprises a plurality of LCP monofilaments 40 arranged side-by-side as a flat cable as best seen in Figure 3.

The axial member 34 limits elongation of the shaft 12 when the catheter 10 is placed in tension. The catheter 10 may be placed in tension when the catheter 10 is

10 retracted in the proximal direction or withdrawn from a patient's vascular system and some resistance to movement is encountered. If the resistance to movement is encountered distal of the proximal end 22, the catheter shaft 12 is placed in tension. When significant tension is applied to the shaft 12, the axial member 34 limits elongation of the shaft. Further, the axial member 34 maintains one-to-one correspondence between

15 axial manipulation of the proximal end 22 and axial movement of the distal end 20 of the shaft 12, even when the catheter 10 is placed in tension. By maintaining one-to-one correspondence in axial manipulation, the axial member 34 maintains precise control of the catheter 10.

Not only does the axial member 34 limit elongation of the shaft 12 and maintain

20 precise control of the catheter 10, by positioning the axial member 34 between the helical members 32A and 32B, the axial member 34 does not create a radial protrusion or become fixed to an adjacent polymer layer, both of which may create undesirable effects.

Specifically, if the axial member 34 were placed over or under the helical

members 32, a radial protrusion may extend along the length of the inner layer 36 or the outer layer 30. Such a protrusion along the inside surface of the catheter 10 may not be desirable because it may create friction or bias with devices inserted into the lumen 18. In addition, a protrusion along the outside surface of the catheter 10 may not be desirable because it may create friction, bias, or prevent adequate sealing with devices that the catheter 10 is inserted into. By positioning the axial member 34 between the helical members 32A and 32B, no protrusions are formed thereby maintaining low friction and adequate sealing.

Further, if the axial member 34 were positioned under or over the helical members 32A and 32B, the inner layer 36 or the outer layer 30 may become fixed to the axial member 34, thereby limiting relative movement and flexure therebetween. Limiting relative movement and flexure may cause excessive stiffness in one or more planes of flexure. This may cause difficulties in manipulating and navigating the catheter 10 through tortuous vasculature. By positioning the axial member 34 between the helical members 32A and 32B, relative movement therebetween is permitted thereby maintaining some amount of flexibility.

The outer layer 30 may be formed of any suitable polymer such as polyether block amide having a wall thickness of approximately 0.0025 inches. The outer layer 30 may be loaded with a radiopaque contrast material such as barium sulfate, preferably loaded at 30% by weight. The outer layer 30 may be formed by interrupted layer coextrusion (ILC) as described in U.S. Patent No. 5,622,665 to Wang, which is hereby incorporated by reference. The outer layer 30 may include a proximal portion formed of a relatively high durometer polymer and a distal portion formed of a relatively low

durometer polymer. For example, the proximal ILC portion may be formed of PEBAX™ 7233, which has a durometer of 72D and the distal ILC portion may be formed of PEBAX™ 3533 having a durometer of 35D. By virtue of the ILC process, the outer layer 30 gradually transitions from the relatively high durometer polymer to the relatively low durometer polymer, thereby gradually decreasing stiffness distally.

A radiopaque marker band (not shown) may be provided at the distal end 20 of the shaft 12. Such a radiopaque marker band may be formed of gold, tungsten, iridium, or an alloy thereof. The radiopaque marker band may be disposed over the braid 50 and encapsulated by the outer layer 30. The radiopaque marker may be swaged onto or adhesively secured to the braid layer 50. A radiopaque marker band facilitates radiographic visualization and navigation as discussed previously.

The catheter 10 may be manufactured by a number of suitable manufacturing processes including the process described hereinafter. The inner layer 36 and the tie layer 38 may be obtained prefabricated from a suitable vendor, such as H.V. Technologies, and provided as discrete tubes or on a spool as a continuous tube. The helical members 32 are then braided over a carrier (e.g., the tube comprising the inner layer 36 and tie layer 38) with the axial member 34 therebetween as described in greater detail hereinafter. The braided subassembly is subsequently cut to the desired length. A marker band is slid over the braid reinforcement layer 50 into position adjacent the distal end 20 of the elongate shaft 12. The outer layer 30 comprising a prefabricated ILC tube is slid over the braid reinforcement layer 50. A heat shrink tube (e.g., FEP) is then placed over the shaft 12 components and the composite subassembly is pulled through a heated die. The die is heated to 380° - 430° F causing the components of the shaft 12 to be fused

and compressed together by the combined heat and compressive radial force. The heat shrink tube is then removed, exposing the completed shaft 12 subassembly. The manifold 24 and the strain relief 28 are then attached to the proximal end 22 of the elongate shaft 12 using conventional techniques. The distal end 20 of the elongate shaft 12 is then trimmed to the desired length and a soft tip is thermally fused thereto. A lubricious coating is then applied to the exterior of the catheter shaft 12.

As mentioned above, the helical members 32 are braided over a carrier with the axial member 34 therebetween. Although braiding helical members is well known in the art, positioning an axial member between the helical members requires some modification to conventional braiding machines. For example, a conventional Steeger braiding machine may be modified to incorporate an individual bobbin carrier that delivers the axial member 34 through a horn gear shaft. The axial member 34 carrier is retrofitted onto the horn gear. With this arrangement, one of the helical member 32A carriers is allowed to pass under and the other helical member 32B carrier is allowed to pass over the axial member 34. The net result is a braid reinforcement structure comprising two or more interwoven helical members 32, with an axial member 34 disposed therebetween.

From the foregoing, it should be apparent to those skilled in the art that the present invention provides both a novel intravascular catheter 10 and a novel method of manufacture thereof. The catheter 10 comprises an elongate shaft 12 including a braid reinforcement 50 with an axial member 34 disposed between helical members 32 that form the braid 50. The axial member 34 limits axial strain of the shaft 12 thereby minimizing elongation of the catheter 10 and maintains one-to-one correspondence

between axial manipulation and movement of the catheter 10, even when the shaft 12 is placed in tension. By positioning the axial member 34 between the helical members 32, the axial member 34 does not create the undesirable effects of friction caused by a radial protrusion and further does not create the undesirable effects of limited flexure caused by an adjacent polymer 30 or 36 becoming fixed to the axial member 34.

Those skilled in the art will recognize that the present invention may be manifested in a variety of forms other than the specific embodiments described and contemplated herein. Accordingly, departures in form and detail may be made without departing from the scope and spirit of the present invention as described in the appended claims.